U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

September 26, 2014

BY ECF

Honorable Colleen McMahon
United States District Judge
United States Courthouse
500 Pearl Street, Room
New York, NY 10007

Re: *United States* ex rel. *Kester v. Novartis Pharmaceuticals Corp.*, 11 Civ. 8196 (CM)(JCF)

Dear Judge McMahon:

This Office represents the United States (the "Government") in the above-referenced action. At the September 19 pre-trial conference, Novartis requested that the Court separate the Government's case into two trials, one for the Myfortic kickback scheme and one for the Exjade kickback scheme. The Government objects to Novartis's request and, pursuant to the Court's direction at the September 19 conference, respectfully submits this letter to set forth why separating this case into two trials is not warranted under Federal Rule of Civil Procedure 42(b).

Briefly, as separation under Rule 42(b) "is the exception, not the rule," Novartis must show how exceptional circumstances make separate trials "*necessary*" here. Novartis cannot make that showing. The Government's Myfortic and Exjade claims present common factual questions – including whether the two schemes reflected an overarching strategy or plan and whether Novartis acted with the requisite *scienter* – that will involve the same witnesses and documentary evidence as well as the same legal issues. Thus, having separate trials will require the Court to empanel two juries to review the same evidence, resulting in an unnecessary waste of the Court's resources and the jurors' time. *See infra* at 2-4.

Balanced against such wastefulness, Novartis cannot identify any confusion to the jury or undue prejudice to Novartis that is likely to result from having a single trial. The very evidence that Novartis seeks to keep from a jury by having separate trials nonetheless is likely to be admissible whether there is one trial or two. For example, even in a separate Myfortic trial, evidence of the Exjade scheme would be admissible to rebut any suggestion by Novartis that its unlawful relationships with the Myfortic pharmacies was merely the result of mistakes or oversight by low-level employees. *See* FED. R. EVID. 404(b) (other acts evidence may be admitted for "proving motive … plan … [or] absence of mistake"). In other words, it is both reasonable and efficient – given the interrelationship between the two schemes on matters of motive, plan, and absence of mistake – to try the two schemes together, and both inefficient and potentially prejudicial to the Government to try them separately. *See infra* at 4-5. For these reasons, we respectfully submit that Novartis's request for separate trials be denied.

I. Under Rule 42(b), Novartis Must Show That Exceptional Circumstances Make It Necessary to Have Two Separate Trials

Under Rule 42(b), separating issues for trial "is the exception, not the rule." *Blessing v. Sirius XM Radio Inc.*, 756 F. Supp. 2d 445, 460 (S.D.N.Y. 2010); *see also* FED. R. CIV. P.

42(b), advisory committee note ("separation of issues for trial is not to be routinely ordered"). Under the federal rules, "the fundamental presumption [] favors the trial of all issues to a single jury." *Monaghan v. SZS 33 Assoc.*, L.P., 827 F. Supp. 233, 246 (S.D.N.Y. 1993); *see also Miller v. Am. Bonding Co.*, 257 U.S. 304, 308 (1921) ("The general practice is to try all the issues in a case at one time"); *Lewis v. City of New York*, 689 F. Supp. 2d 417, 428 (E.D.N.Y. 2010). ("[o]rdinarily, a jury is entitled to hear all of the evidence and deliberate over all of the issues in the case at one time"). Thus, "the party moving for [] separate trial[s] has the burden of showing that [such separation] is necessary.'" *Gaffney v. Dep't of Info. Tech. & Telecommunications*, 579 F. Supp. 2d 455, 459 (S.D.N.Y. 2008); *see also Monaghan*, 827 F. Supp. at 246 (under Rule 42(b), having separate trials "is reserved for truly extraordinary situations of *undue* prejudice").

The decision over whether to order separate trials is charged to this Court's discretion. *See Simpson v. Pittsburgh Corning Corp.*, 901 F.2d 277, 283 (2d Cir. 1990) (district court "acted well within [its] discretion in denying bifurcation"). In this District, courts consider four factors in assessing a request for separate trials:

> (1) whether the issues sought to be tried separately are significantly different from one another; (2) whether the severable issues require testimony from different witnesses and different documentary proof; (3) whether the party opposing the severance would be prejudiced if it is granted; and (4) whether the party requesting the severance would be prejudiced if it is not granted.

BD ex rel. Jean Doe v. DeBuono, 193 F.R.D. 117, 125 (S.D.N.Y. 2000) (McMahon, J.); *see also Gaffney*, 579 F. Supp. 2d at 459 (same).

II. The Myfortic and Exjade Schemes Involve Significant Level of Overlapping Evidence and Present the Same Legal Issues

At the September 19 conference, Novartis suggested that there is no overlap of witness or documentary evidence for the Myfortic and Exjade kickback schemes. This is wrong — common factual issues involving the same witnesses and same documents will be relevant to both schemes. For example, it is highly relevant to *scienter* (*i*) whether the Myfortic and Exjade schemes reflected Novartis's overarching strategy or plan to "leverage[]" the "the role of pharmacist … to influence marketing opportunities," and (*ii*) whether these schemes contravened Novartis's compliance policies and its Corporate Integrity Agreement with HHS-OIG.

First, it was not a coincidence that the Myfortic and Exjade schemes both involved efforts by Novartis executives to give inducements to specialty pharmacies in exchange for recommendations. At trial, the Government will present evidence, including internal Novartis documents, showing those efforts reflected a strategy at the corporate-level at Novartis to "leverage[]" the "the role of the pharmacist … to influence marketing opportunities" using many of the same tactics, *e.g.*, deciding whether to offer inducements to pharmacies based on the "return on investment," or "ROI," from such improper relationships. The evidence also will show that this strategy was implemented by the Commercial Contracting & Analysis group ("CC&A") at Novartis in coordination with the "managed markets" groups within the oncology and general medicine divisions. More specifically, the Government expects to call fact witnesses from each of those groups – which may include CC&A executives such as Robert Chinn and Susan Gleason, general medicine managed markets executives such as Mark Smith, and oncology managed markets executives such as Paul Pochtar and Kenneth Olsen – to show the

existence and contours of Novartis's overarching strategy for both Myfortic and Exjade.

Second, to assess Novartis's *scienter*, the jury also is entitled to consider evidence concerning whether the Novartis employees orchestrating the Myfortic and Exjade kickback schemes either knew that those schemes violated internal compliance policies or deliberately or recklessly disregarded "red flags" suggesting likely violations. *See In re Veeco Instruments, Inc., Sec. Litg*., 235 F.R.D. 220, 231-32 (S.D.N.Y. 2006) (McMahon, J.) (citing *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 77 (2d Cir. 2001)). Thus, at trial, the Government expects to present evidence – in relation to both schemes – on the requirements regarding kickback compliance in Novartis's compliance policies and under the Corporate Integrity Agreement, as well as the types of relationships that raised concerns under those policies. At the September 19 conference, Novartis suggested that there is no need for this evidence at trial because it will stipulate to having an anti-kickback policy. Such a generic stipulation, however, is plainly insufficient because the jury is entitled to compare the specific requirements or warnings communicated to the relevant employees at Novartis with the particulars of the improper arrangements made by those employees.

In addition, as the Court has held, the Government's claims under the False Claims Act involve false certifications made by pharmacies like Transcript and BioScrip to receive reimbursements from Medicare and Medicaid. *See*, *e.g.*, *Novartis I* at 32-33 [Dkt. 192]. Thus, the jury will need to have a basic understanding of:

- How pharmacies submitted Medicare and Medicaid claims and received reimbursements;
- Certifications the pharmacies submitted to Medicare and Medicaid; and
- Novartis's knowledge of Medicare and Medicaid coverage for Myfortic and Exjade.

Having separate trials for Myfortic and Exjade will require the Court and two different juries to listen to the same witnesses going over essentially the same evidence regarding these issues.[1]

Finally, besides these common factual issues, the jury will need to apply – and have to be instructed on – the same legal principles that go to the crux of the Government's Myfortic and Exjade claims and Novartis's defenses. Under both schemes, Novartis gave inducements to specialty pharmacies for recommending Novartis drugs, and the pharmacies then certified that no kickbacks were given or offered. Thus, for both schemes, the jury will be instructed on how to determine whether the inducements, including rebates, were kickbacks. Moreover, Novartis has

[1] The main difference between the Myfortic and Exjade schemes in terms of factual issue is that the Exjade scheme involved Novartis using, in addition to rebates, patient referrals as a form of kickbacks to induce the pharmacy to recommend. But that one variation in the structure of the kickback schemes, which a jury can easily grasp, is outweighed by the significant overlapping factual issues relevant to both schemes. Indeed, courts routinely refuse to order separate trials even where there is not even a single defendant in common between the claims to be tried together, explaining that what matters is not whether all the claims involve *all* the same evidence, but instead whether "at least some of the testimony and witnesses will be identical." *Blessing*, 756 F. Supp. 2d at 460; *accord DeBuono*, 193 F.R.D. at 126 (where the claims overlap as to even "some evidence," this factor "weighs against severance").

proffered the same legal defenses to the Government's Exjade and Myfortic claims. *See* Novartis Answer to Gov't Amend. Compl. at 39-42 [Dkt. 250]. Those include, significantly, the argument that the rebates were within the statutory exception and related regulatory "safe harbor" for discounts. *See id*.

In light of these significant overlaps in factual issues and legal questions, having separate trials for Myfortic and Exjade will impose substantial waste in terms of judicial resources and the jurors' time. *See*, *e.g.*, *Blessing*, 756 F. Supp. 2d at 460-61 (denying motion for separate trials where it would require "two submissions of pretrial materials involving inevitable redundancies . . . twice the number of jurors, and likely two rounds of post-trial briefing"); *DeBuono*, 193 F.R.D. at 125 (denying motion for separate trials, in part, because it would impose duplicative burdens on judicial resources).

III. Trying the Myfortic and Exjade Schemes Together Will Not Cause Undue Prejudice or Confusion, But Separate Trials Could Prejudice the Government

At the September 19 conference, Novartis did not articulate any reason for supposing that any confusion or undue prejudice would result from the Court following the "general practice" and "try[ing] all the issues in [the Government's case] at one time." *Miller*, 257 U.S. at 308. Indeed, as Novartis acknowledged, the two kickbacks schemes involve drugs with different names, used for different conditions, and distributed through different pharmacies. Thus, it is unlikely that a jury could confuse the two schemes. *See In re: Blech Sec. Litig*., 94 Civ. 7696 (RSW), 2003 WL 1610775, at *14 (S.D.N.Y. Mar. 26, 2003) (recognizing that "jury confusion is less likely since there are only two active defendants").

Given these differences, there also is little risk of any undue prejudice to Novartis — especially because, as discussed above, the evidence will show that the two schemes reflected an overarching corporate strategy. *See id*. (explaining that there is "no prejudice" from trying claims together "when the claims, witnesses, and evidence overlap … because the evidence on one claim is relevant and necessary to established an independent but interrelated claim"). Indeed, at trial, the evidence of the two schemes will come together to show an overall strategy by Novartis to improperly leverage pharmacies' influence using kickbacks. Evidence of Novartis's actions in one scheme, thus, will be relevant to the company's "motive [or] plan" in the other scheme. *See*, *e.g.*, *Lewis v. Triborough Bridge and Tunnel Auth*., 97 Civ. 0607 (PKL), 2000 WL 423517, at *5 (S.D.N.Y. Apr. 19, 2000) (where plaintiffs allege a "pattern of conduct," evidence concerning one claim in the pattern is admissible to other claims within the overall pattern). Further, because Novartis likely will try to minimize its *scienter* with regard to each kickback scheme by attributing the improper relationships to mistakes or oversights by low-level employees, the evidence of the other scheme could be admitted to "prov[e] absence of mistake [] or lack of accident." FED. R. EVID. 404(b); *see also Alaniz v. Zamora-Quezada*, 591 F.3d 761, 774 (5th Cir. 2009) (affirming denial of separate trials where evidence of a defendant's conduct from other contexts was admissible under Rule 404(b)).[2]

In sum, Novartis cannot show that trying the Myfortic and Exjade claims together is

[2] Of course, the Court need not decide these questions of admissibility at this juncture. But the connection between the Myfortic and Exjade schemes on matters of motive, plan, and corporate strategy (and the other overlapping factual issues discussed above) undercuts any suggestion that Novartis somehow be unduly prejudiced by having one trial for both the schemes.

likely to cause any confusion to the jury or any undue prejudice to Novartis, much less the "extraordinary situations" that courts have required to depart from the "presumption" of trying "all issues to a single jury." *Monaghan*, 827 F. Supp. at 246. By contrast, having separate trials – despite the connection between the two schemes – would require the Government to present the same evidence twice, which is inefficient and prejudicial. *See Sterling Const. Management, LLC v. Steadfast Ins. Co*., 280 F.R.D. 576, 580-81 (D. Colo. 2011) (recognizing prejudice to non-moving party from "having to participate in two trials and to call witnesses twice").

* * *

For the reasons set forth above, the Government submits that the Court should deny Novartis's request under Rule 42(b) for having separate trials for the Myfortic and Exjade schemes and, instead, allow those schemes to be tried together. We thank the Court for its consideration of this letter.

Respectfully,

PREET BHARARA
United States Attorney

By: _____/s/_____
LI YU
REBECCA C. MARTIN
ROBERT YALEN
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, NY 10007
Tel.: (212) 637-2734/2714/2722

cc: (By ECF)
Evan Chesler (Cravath, Swaine & Moore LLP)
Nina M. Dillon (Cravath, Swaine & Moore LLP)
Rachel G. Skaistis (Cravath, Swaine & Moore LLP)
Faith Gay (Quinn Emanuel Urquhart & Sullivan LLP)
Manisha M. Sheth (Quinn Emanuel Urquhart & Sullivan LLP)
Michael Rogoff (Kaye Scholer LLP)
Manvin Mayell (Kaye Scholer LLP)
Steven U. Ross (California)
Christopher Y. Miller (New York)
Diana Elkind (New York)
Carrie Barshaw (Washington)
Shelley R. Slade (Vogel, Slade & Goldstein LLP)
Arun Subramanian (Susman Godfrey LLP)
Steven Shepherd (Susman Godfrey LLP)
Daniel Meron (Latham & Watkins LLP)
Allen Gardner (Latham & Watkins LLP)
Enu Mainigani (Williams & Connolly)